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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/917,897      | 07/31/2001  | Masashi Ogawa        | Q65704              | 2025             |

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MORAN, MARJORIE A

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

9

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                  |
|------------------------------|-------------------------------|------------------|
| <b>Office Action Summary</b> | Application No.               | Applicant(s)     |
|                              | 09/917,897                    | OGAWA ET AL.     |
|                              | Examiner<br>Marjorie A. Moran | Art Unit<br>1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 28 April 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 3 and 5 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 3 and 5 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. 09/125,944.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

All rejections and objections not reiterated below are hereby withdrawn.

***Information Disclosure Statement***

The examiner acknowledges receipt of an International Search Report and a European Search Report which apparently were preformed for a Japanese application. As these search reports have not been properly cited on an IDS (Form PTO 1449), they have not been considered.

***Terminal Disclaimer***

The terminal disclaimer filed on 4/28/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,485,926 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by GALIS et al. (FASEB (7/1995), volume 9, pages 974-980).

GALIS teaches a method of detecting a protease in a biological sample wherein consecutive sections of the sample are brought into contact with a thin membrane comprising a support holding a fluorescent substrate mixed with agarose, and other sections are brought into contact with similar thin membranes with protease inhibitors incorporated, and the results from the two are compared (p. 975: Protocol and Controls). GALIS teaches that his agarose is used to stabilize his substrate film (p. 977); as agarose is well-known to be "hard" at room temperature, it is a 'hardening agent,' and claim 3 is anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over GALIS et al. (FASEB (7/1995), volume 9, pages 974-980) in view of TERASHIMA et al (US 4,839,278) and LAWRENCE et al. (IDS ref: US 5,416,003).

Claim 3 recites a method of detecting a protease in a biological sample by contacting one of multiple continuous slices of the sample with a thin membrane comprising a protease substrate and a hardener on a support, contacting the remaining slices of the sample with a similar thin membrane which also comprises a protease inhibitor, detecting traces of digestion on the membranes, and comparing the two.

Claim 5 recites a similar method wherein a sample (not limited to be slices) is contacted by a thin membrane comprising layers laminated together on a support, wherein one layer comprises a protease substrate and a hardener, and a second layer comprises a substrate, hardener, and inhibitor, and the traces of digestion on the two layers are detected and compared.

GALIS teaches a method of detecting a protease in a biological sample wherein consecutive sections of the sample are brought into contact with a thin membrane comprising a support holding a fluorescent substrate mixed with agarose, and other sections are brought into contact with similar thin membranes with protease inhibitors incorporated, and the results from the two are compared (p. 975: Protocol and Controls). GALIS teaches that his agarose stabilizes the substrate film (p. 977), and is

interpreted to be a hardening agent, as set forth above. GALIS does not teach a multiply layered thin film.

LAWRENCE teaches a device for detecting proteases in samples wherein multiple layers are laminated together, and wherein one layer may comprise a substrate and another layer may comprise an inhibitor (col. 23, lines 55-62 and col. 24, lines 34-39).

TERASHIMA teaches a variety of reagents for cross-linking (hardening) gelatin on a thin film, and teaches that these are similar in function to agarose (col. 6, line 59-col. 7, line 15).

It would have been obvious to one of ordinary skill in the art at the time of invention to have laminated a layer comprising a substrate, hardener, and inhibitor to a layer comprising a substrate, hardener, and inhibitor in a multiplayer analytical element, as taught by LAWRENCE, for use in the method of GALIS where the motivation would have been to facilitate measurement of protease in a single sample using a single test element, as suggested by the teaching of LAWRENCE that a test element comprising laminated layers can be used to detect proteases. It would further have been obvious to have used any of the crosslinkers of TERASHIMA as the stabilizer for gelatin in separate test elements, as taught by GALIS or a single test element comprising laminated layers, as taught by LAWRENCE, in the method of GALIS, where the motivation would have been to use any crosslinker or "hardening agent" known to stabilize gelatin such that it does not dissolve or liquefy during activity measurement, as taught by both TERASHIMA (col. 6, lines 59-68) and GALIS (p. 977). No unexpected

result or criticality has been shown for use of any particular hardening agent in the method.

***Conclusion***

Claims 3 and 5 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Specifically, as the claims have been amended to recite "detection" instead of "measurement", the prior art rejections set forth above now apply to the instant claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.



MARJORIE MORAN  
PATENT EXAMINER

mam  
June 19, 2003